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MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122			MYERS, CARLA J	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/034,882	PFOST, DALE R.
	<b>Examiner</b>	<b>Art Unit</b>
	Carla Myers	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 17 December 2004.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-27 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

### **DETAILED ACTION**

1. This action is in response to the amendment filed December 17, 2004. Claims 1-27 are pending. All rejections not reiterated herein are hereby withdrawn. Applicant's amendments and arguments have been fully considered but are not persuasive to overcome all grounds of rejection. This action is made final.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to compositions of compounds effective for treating a pathology, said composition comprising at least two compounds (or 3 or 4 or 5 or 6 compounds) that modulate the activity of one or more target compounds associated with a SNP.

*Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." Applicant is reminded that Vas-

Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention."

In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, no members of the broadly claimed genus of compounds have been defined by their structure. The specification (see Examples 1 and 2) discusses the use of drugs A, B, C, D and E and the response of patients having a different genotype to these drugs. However, the specification does not disclose the identity of these drugs, which SNPs the drugs are associated with, what pathology the drugs treat, or the genotype of the patients. Accordingly, the specification does not provide an adequate written description of a single composition within the scope of the claimed invention.

It is then determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. restriction map, specific biological activity of an encoded protein product, etc.). In the instant case, no such identifying characteristics have been provided for any of the compounds.

Accordingly, the written description requirements have not been met for the genus claimed because a representative number of compounds within the claimed genus have not been defined in terms of their structure or other specific identifying characteristics. While the breadth of the claims is not reasonably quantifiable, it is clear that the genus of compounds that may be included by the claims is enormous. The claims allow for compounds "effective for treating a pathology." Thereby, the claims include compounds that treat any of the diverse pathologies, such as diabetes, Alzheimer's Disease, Cancer, Parkinson's Disease, lupus, AIDS, MS, allergies, malnutrition, depression, drug addiction, gingivitis, epilepsy, etc. etc.... The composition may be used to treat a pathology in a human or any other type of animal. The claims include any type of compound that can be "used to effect a physiological change in treating a pathology" (page 5). Thus, the claims include any type of inorganic or organic compound, such as antisense molecules, antibodies, DNA molecules used for gene therapy, vaccines, enzymes, and receptors. The compounds are defined in terms of modulating the activity of one or more target molecules. The target molecules, may again, be of any structure. As discussed in the specification (page 6), the target molecule "can vary from as large as an association molecules, such as a ribosome or a lipid bilayer, to as small as a small molecule or an ion, such as a hormone, cytokine,

cAMP, NO, Ca<sup>2+</sup>, K<sup>+</sup>, phosphate, and the like." The compound may modulate the activity of the target compound by any manner. For instance, the specification (page 6) teaches that the compounds may increase or decrease enzyme activity, may increase or decrease gene expression, may increase or decrease protein-protein interaction, may increase or decrease signal transduction, or may increase or decrease transport or translocation across the membrane. The target compound is described as being associated with one or more SNPs. The relationship between the target compound and SNP is not defined. The claims thereby include target compounds that are in any way related, directly or indirectly, specifically or nonspecifically, with a SNP. The SNP may also be from any gene or protein and may be at any location within the gene or protein.

The specification does not disclose a common structural feature linking the claimed genus of compounds. The claims define the compounds in terms of their functional activity, but do not define any of the structural properties of the compounds. While a limited number of specific individual compounds are known in the art which directly modulate the activity of nucleic acids or proteins containing SNPs, the general knowledge in the art concerning therapeutic compounds does not provide any indication of how the structure of one therapeutic compound is representative of other therapeutic compounds. The structure and function of a given compound that modulates the activity of one SNP does not provide guidance as to the structure and function of other compounds that modulate the activity of the same or other SNPs. Therefore, the description in the prior art of specific therapeutic compounds is not

representative of the very large genus of compositions containing two or more compounds that are effective for treating a pathology.

Additionally, the claims include compositions that are effective for treating at least 1%, 25%, 50%, 75% or 90% of patients having the pathology. Yet, the specification does not disclose a common structural feature or specific property that is present in compounds and which ensures the compounds are effective for treating at least 1%, 25%, 50%, 75% or 90% of patients having the pathology. The claims further include compounds that are stably effective for at least 50%, 75%, or 90% of the patients having the pathology. The specification at page 12 defines stably effective as including compounds whose effectiveness does not change over a time scale of 1, 2, 5, 10, 25, 50 or 100 years. However, the specification does not define any particular structural feature which ensures the property that the compounds are stably effective for at least 50%, 75%, or 90% of the patients having the pathology.

For these reasons, Applicants have not provided sufficient evidence that they were in possession, at the time of filing, of the invention as it is broadly claimed and thus the written description requirement has not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, 1 Written Description Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

**Response to Arguments:**

In the response filed December 17, 2004, Applicants traversed this rejection by arguing that the specification provides a written description of compounds suitable for

inclusion in a composition of the present invention. It is asserted that the specification teaches the properties of compounds to be included by the present invention, including compounds directed to modulating the activity of a target molecule and that such compounds preferably include amounts of two or more compounds that when combined effectively treat an optimum number of patients. It is argued that because the specification exemplifies compounds that meet the limitations of the present compositions, the written description requirements have been met.

Applicants arguments have been fully considered but are not persuasive to overcome the present grounds of rejection for the following reasons. Contrary to Applicants arguments, Applicants have not in fact exemplified a composition having each of the elements of the claimed invention. The specification (see Examples 1 and 2) discusses the use of drugs A, B, C, D and E and the response of patients having a different genotype to these drugs. However, the specification does not disclose the identity of these drugs, which SNPs the drugs are associated with, what pathology the drugs treat, or the genotype of the patients. A reference to a generic compound in terms of that compound being drug A, B, C, D and E does not provide a clear definition of that drug in terms of its structure and function. Accordingly, the specification does not provide an adequate written description of a single composition within the scope of the claimed invention. Even if compounds A, B,C,D and E were clearly defined in the specification in terms of their structure and function, the claims are not limited to these compounds. The disclosure in the specification of 5 compounds is not representative of the broadly claimed genus of a composition comprising 2 compounds that modulate the

activity of any SNP, to levels such that the combination of compounds effectively treats at least 90% of the patients having the pathology. Again, the claims do not recite the identity of the compound that modulates activity, the claims do not recite a particular activity, the claims do not recite the identity of gene comprising a SNP, the claims do not recite the identity of the SNP, and the claims do not recite any particular pathology. Thereby, the disclosure in the specification of a desire to obtain a composition comprising a combination of compounds that modulate the activity of a target molecule that is associated with a SNP is not sufficient to meet the written description guidelines in view of the fact that the specification does not teach a representative number of such compositions and the claims and specification do not characterize such compounds in terms of any structural properties.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions consisting of the specific HIV vaccine set forth in U.S. Patent No. 5,846,546 and the HBV antibody composition set forth in U.S. Patent No. 5,648,077 (it is noted that the specification does not provide support for the disclosure of these compositions; enablement is provided only via the disclosure of the '546 and '077 patents), does not reasonably provide enablement for compositions containing any two or more compounds that are to be used to effectively treat any pathology, wherein the compounds modulate the activity of one or more target

compounds associated with any SNP. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in formulating this rejection (*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

The claims are broadly drawn to compositions of compounds effective for treating a pathology, said composition comprising at least two compounds (or 3 or 4 or 5 or 6 compounds) that modulate the activity of one or more target compounds associated with a SNP. The specification does not adequately teach one of skill in the art how to make and use the claimed genus of compositions without undue experimentation for the following reasons.

The breadth of the claims is significantly large. The claims require 2 or more compounds "effective for treating a pathology." Thereby, the claims include compounds that treat any of the diverse pathologies, such as diabetes, Alzheimer's Disease, Cancer, Parkinson's Disease, lupus, AIDS, MS, allergies, malnutrition, depression, drug addiction, gingivitis, epilepsy, etc. etc.... The composition may be used to treat a pathology in a human or any other type of animal. The claims include any type of compound that can be "used to effect a physiological change in treating a pathology"

(page 5). Thereby ,the claims include any type of inorganic or organic compound, such as antisense molecules, antibodies, DNA molecules used for gene therapy, vaccines, enzymes, and receptors. The compounds are defined in terms of modulating the activity of one or more target molecules. The target molecules, may again, be of any structure. As discussed in the specification (page 6), the target molecule "can vary from as large as an association molecules, such as a ribosome or a lipid bilayer, to as small as a small molecule or an ion, such as a hormone, cytokine, cAMP, NO,  $\text{Ca}^{2+}$ ,  $\text{K}^+$ , phosphate, and the like." The compound may modulate the activity of the target compound by any manner. For instance, the specification (page 6) teaches that the compounds may increase or decrease enzyme activity, may increase or decrease gene expression, may increase or decrease protein-protein interaction, may increase or decrease signal transduction, or may increase or decrease transport or translocation across the membrane. The target compound is described as being associated with one or more SNPs. The relationship between the target compound and SNP is not defined. The claims thereby include target compounds that are in any way related, directly or indirectly, specifically or nonspecifically, with a SNP. The SNP may also be from any gene or protein and may be at any location within the gene or protein. Additionally, the claims include compositions that are effective for treating at least 1%, 25%, 50%, 75% or 90% of patients having the pathology. Yet, the specification does not disclose a common structural feature or specific property that is present in compounds and which ensures the compounds are effective for treating at least 1%, 255, 50%, 75% or 90% of patients having the pathology. The claims further include compounds that are stably

effective for at least 50%, 75%, or 90% of the patients having the pathology. The specification at page 12 defines stably effective as including compounds whose effectiveness does not change over a time scale of 1, 2, 5, 10, 25, 50 or 100 years. However, the specification does not define any particular structural feature which ensures the property that the compounds are stably effective for at least 50%, 75%, or 90% of the patients having the pathology.

Accordingly, the claims encompass a phenomenally large genus of compounds that are not defined in terms of any specific structural property. Yet, the specification does not provide a single example of a specific compound that falls within the scope of the claims. The specification (see Examples 1 and 2) discusses the use of drugs A, B, C, D and E and the response of patients having a different genotype to these drugs. However, the specification does not disclose the identity of these drugs, which SNPs the drugs are associated with, what pathology the drugs treat, or the genotype of the patients. Rather, the specification provides a general description of a research project which one might undertake in order to try to identify compositions which fall within the scope of the claims. For example, the specification (page 10) states that methods for identifying SNPs are known in the art. It is also stated that methods are known in the art for analyzing a SNP in order to determine if it is associated with a pathology (page 11). Once a SNP associated with a disease has been identified, one should then screen compounds, *in vitro* or *in vivo*, in order to try to identify compounds that may be effective at modulating the activity of a target molecule (pages 14 and 18). The specification

teaches that compounds should be selected which, when used in combination, remain effective and do not result in a toxic response.

Clearly, the described research project provides only an invitation to experiment. While methods for analyzing SNPs and therapeutic compounds may be known in the art, providing methods of searching for compounds is not equivalent to providing specific compounds that can be used to treat specific pathologies by modulating the activity of specific target molecules correlated with specific SNPs.

The art of identifying therapeutic compounds that modulate the activity of a molecule associated with a SNP is highly unpredictable. There is no common structural feature which links therapeutic compounds and which would allow one to ascertain a priori whether a compound will modulate the activity, expression etc of a target molecule that is directly or indirectly associated with a SNP. Given the lack of a specific structure-function relationship between SNPs and the occurrence of a pathology, the lack of a specific structure-function relationship between therapeutic compounds and the ability to modulate target molecules and the lack of a specific structure-function relationship between therapeutic compounds and the ability to treat a pathology, one can only identify SNPs, target molecules and therapeutic compounds through extensive experimentation. Additionally, the specification does not provide any specific guidance as to how to identify compounds that have these attributes when used in combination. Combinations of compounds can only be identified through random, trial-by-error experimentation. The specification emphasizes the unpredictability of identifying compounds that can be used in combination to effectively treat a pathology. The

specification points out that each compound will may have a different effect, such that the effect of one compound may negate the effect a second compound. It is also well known and accepted in the art that compounds may interfere with one another and may in combination cause toxic side-effects. The specification does not provide any guidance as to how to determine a priori which combinations of two, three, four, five, six or more compounds can be used together to effectively treat a pathology. Such information can be obtained only through experimentation.

Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". In the instant case, the state of the art , the specification does not provide the novel aspects of the invention. Rather, the novel aspects of the invention can only be supplied through extensive experimentation. In view of the high level of unpredictability in the art and the lack of specific guidance and working

examples provided in the specification, undue experimentation would be required to practice the broadly claimed invention.

**Response to Arguments:**

In the response filed December 17, 2004, Applicants traversed this rejection by arguing that the specification teaches methodologies for identifying SNPs, including hybridization, SSCP, denaturing HPLC and DNA arrays and provides guidance as to how to identify a SNP by comparing the sequence of a target gene to a wildtype gene. It is further argued that methods are known in the art for ascertaining whether a SNP is associated with a pathology. Applicants cite Hijikata and Lambert as teaching methods for identifying a SNP. Applicants argue that once a SNP is found to be associated with a pathology, compounds that target the pathology can be obtained. For example, once a protease with a SNP is identified, a protease inhibitor can be prepared, a composition can be made that contains at least 2 compounds, and these compounds can then assayed to determine if together the compounds effectively treat a pathology. It is asserted that this experimentation is merely routine.

Applicants arguments have been fully considered but are not persuasive for the following reasons. Applicants assert that numerous known methods can be performed to first identify a SNP, then to determine if a SNP is associated with a pathology, and then to screen for compounds that modulate the activity of the SNP and then to find combinations of compounds that treat a percentage of patients having this pathology. While methods may be known in the art for sequencing genes and for performing linkage and association assays to determine if a SNP is correlated with a pathology,

such teachings provide only the guidelines that enable practitioners to perform experiments to try to identify SNPs and to try to find SNPs associated with a pathology. Such teachings are not equivalent to providing specific SNPs that are associated with specific diseases and providing specific compounds that when used in combination effectively treat up to 90% of the population. The present claims are not drawn to methods of searching for a SNP or trying to determine if a SNP is associated with a disease or methods for searching for compounds that regulate the activity of a SNP. Rather, the present claims are limited to compositions comprising a combination of compounds that modulate the activity of a SNP associated with a pathology. As addressed above, the specification does not exemplify a single compound within the scope of the present invention. While the prior art teaches compounds that modulate the activity of a SNP, such limited teachings directed to specific SNPs associated with specific diseases are not sufficient to support the enablement of the broadly claimed invention of any combination of compounds that modulate in any manner any SNP present in any gene and associated with any pathology. The experimentation required to identify the compounds present in the claimed compositions is extensive and highly unpredictable and would not be considered by the artisan to be routine.

The novel aspect of the claims is the combination of compounds that modulate the activity of a SNP associated with a pathology. The novel aspects of the invention are not the process steps of sequencing to identify a SNP, performing linkage and associated studies to identify SNPs associated with a pathology, or performing general screening methods to identify a compound that modulates the activity of a SNP. Such

general methodologies are well known in the art, as indicated by Applicants teachings in the specification and arguments presented in the response. Accordingly, if the claims are intended to be limited to methods of searching for compounds that fall within the scope of the claims, then such methods of searching would clearly be anticipated and rendered obvious by the prior art.

Applicants have argued that the claimed compositions are fully enabled by the specification because the specification teaches how to search for SNPs, how to identify SNPs associated with disease and how to screen for compounds that modulate the activity of a SNP. However, the specification does not sufficiently characterize the identity of the compounds, SNPs, or pathologies and does not provide sufficient guidance to enable the skilled artisan to use the compositions to effectively treat up to 90% of the population having the pathology. The specification does not adequately teach a relationship between the structure and function of the broadly claimed genus of compounds. There are no teachings in the specification as to which particular combinations of compounds can be used to effectively treat up to 90% of the population having the pathology. The specification provides the artisan with only an invitation to experiment. In view of the high level of unpredictability in the art of identifying SNPs, finding an association between SNPs and particular pathologies and identifying compounds that when used in combination modulate the activity of a SNP and effectively treat up to 90% of the patients having the pathology, and in view of the lack of guidance and working examples provided in the specification, it is maintained that

undue experimentation would be required to practice the invention as it is broadly claimed.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1-27 are indefinite over the recitation of "target molecules associated with one or more Single Nucleotide Polymorphisms (SNPs)." The specification states that a "target molecule that is 'associated with' or 'correlated with' a particular genetic variation, preferably a particular SNP, is a molecule that can be functionally distinguished in its structure, activity, concentration, compartmentalization, secretion, and the like, as a result of such genetic variation." However, this teaching does not provide a clear and complete definition for what is intended to be encompassed by target molecules associated with SNPs. It is unclear as to whether the target molecule contains a SNP (e.g., a nucleic acid or protein that contains a SNP) or if the target molecule is in some other way associated with a SNP (e.g., the target molecule itself does not contain a SNP but other members of this class of compounds contains a SNP, or the target molecule is a part of a cycle / cascade involving numerous other compounds in which one of the other compounds contains a SNP or alters the activity or expression of a SNP or creates the formation of a SNP). Accordingly, it is unclear as to what is intended to be the relationship between the target compound and the SNP.

**Response to Arguments:**

In the response filed December 17, 2004, applicants traversed this rejection by stating that "a target molecule is considered associated with a SNP if the target has a measurable characteristic, which changes in correlation with the presence or absence of a SNP." It is argued that a skilled person familiar with the specification would understand that characteristic can be structure, activity, concentration, compartmentalization, secretion "and the like." However, the broad definition set forth in the specification does not adequately define the phrase "target molecules associated with one or more Single Nucleotide Polymorphisms (SNPs)." Providing examples of what might be encompassed by a characteristic does not provide a complete and fixed definition for such characteristics. These teachings also do not clarify whether the target molecule contains a SNP or if the target molecule is in some other way associated with a SNP. It is maintained that this language is indefinite since it remains unclear as to what is intended to be the relationship between the SNP and the target compound. Accordingly, the artisan cannot determine the meets and bounds of the claimed invention.

B. Claim 7 is indefinite over the recitation of "corresponding" because this is not an art recognized term to describe the relationship between a target molecule and a SNP. It is not clear as to what is intended to be the relationship between the target molecule and the SNP and it is not clear as to whether "the position" constitutes the location of the polymorphism in a nucleic acid or protein or if the position defines some other unstated relationship between the polymorphism and the target molecule.

**Response to Arguments:**

In the response filed December 17, 2004, applicants traversed this rejection by stating the skilled artisan would know that the position is that of the SNP or an amino acid residue encoded by a codon that encompasses said SNP.

This argument has been fully considered but is not persuasive because there are no teachings in the specification which define the term "corresponding" to have the meaning set forth in the response. Further, there is no definition for this term in the art and no teachings in the art which limit this term to have the definition set forth in the response. If the term "corresponding" is intended to refer to the actual SNP or to the amino acid residue encoded by a codon containing the SNP, then the claims should be amended to reflect this concept.

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY  
APPLICANTS AMENDMENTS TO THE CLAIMS:**

C. Claims 17 and 21 are indefinite over the recitation of "further comprising observing modulation effects of said compounds and correlating said modulation effects with the presence of a SNP." The claims have been amended to include process steps, yet the claims are directed to compositions. It is unclear as to how the recited process steps are intended to further limit the properties of the composition.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-27 are rejected under 35 U.S.C. 102(a) or 102(e) as being anticipated by Hurwitz et al (U.S. Patent No. 5,846,546).

Hurwitz discloses HIV vaccines that modulate the activity of target molecules containing SNPs by inducing humoral or cellular immune responses against the target molecule. The vaccines (see, for example, column 2) preferably contain about 10 to 100 recombinant viruses each expressing a different HIV env protein variant (EPV). Each EPV contains a point mutation present in a different strain of HIV (see Table 1). These point mutations are considered to be equivalent to SNPs. Note that page 8 of the present specification defines a SNP as "a genetic variation at a specific site in the genome of an organism, where the nucleotide identity at the site varies between genomic allelic members of a population of organisms." The vaccines are considered to be effective or stably effective for at least 90% of patients having the pathology (i.e., current infection with HIV or susceptibility to infection with HIV; column 29). It is noted that the specification broadly describes what is intended to be encompassed by effective and stably effective. Thereby, "effective" and "stably effective" are considered to encompass any degree of response over any period of time. With respect to claim 7, the claim encompasses any form of indirect interaction between the compound and the target molecule. The ability of the compounds in the vaccine to enhance the cellular and

humoral response to the HIV envelope protein variants thereby constitutes modulation of a target molecule associated with a SNP.

**Response to Arguments:**

In the response filed December 17, 2004, Applicants traversed this rejection by stating the Office action fails to particular point out each of the elements claimed in the invention that are allegedly described in Hurwitz. It is stated that the "vaccines appear to represent the composition of compounds effective for treating a pathology, however they also appear to be representing the one or more target compounds that are associated with one or more Single Nucleotide Polymorphisms (SNPs)." This argument has been fully considered but is not persuasive. It is unclear as to why the teachings of Hurwitz of both the composition for treating the pathology and the target molecules would lead to the conclusion that Hurwitz does not anticipate the claimed invention. Applicants argument does not relate to any particular limitations recited in the claims. As set forth in the above rejection, Hurwitz teaches vaccines (see, for example, column 2) that contain about 10 to 100 recombinant viruses each expressing a different HIV env protein variant (EPV). Each EPV contains a point mutation present in a different strain of HIV (see Table 1) and, given the broad definition of an SNP set forth in the present specification, these point mutations are considered to be equivalent to SNPs. The vaccine is a composition comprising a combination of at least 2 compounds that indirectly modulate the activity of a target protein comprising a SNP. Thereby, Hurwitz teaches a composition having each of the elements of the claimed invention.

6. Claims 1-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Ostberg et al (U.S. Patent No. 5,648,077).

Ostberg discloses a composition comprising antibodies against HBV wherein said composition is effective for treating humans infected with Hepatitis B virus (column 2). The compositions preferably contain a cocktail of antibodies that bind with different variant genes of different HBV strains. The antibodies are encoded by DNA sequences having any of the CDR1, CDR2, or CDR3 regions set forth in Tables 8-1, 8-2, 8-3, and 8-4 and any of the V light chains set forth in Tables 9-1, 9-2, 9-3 and 9-4. Such compositions would thereby comprise at least 6 antibodies. Preferably the compositions comprise at least the antibodies PE1-1, ZM1-1, ZM1-2, MD3-4 and L03-3 (see, for example, columns 3-4). Each antibody binds to a HBV protein having a point mutation present in a different strain of HBV (see, for example, column 3-4). These point mutations are considered to be equivalent to SNPs. Note that page 8 of the present specification defines a SNP as "a genetic variation at a specific site in the genome of an organism, where the nucleotide identity at the site varies between genomic allelic members of a population of organisms." The compositions containing mixtures of HBV antibodies are considered to be effective or stably effective for at least 90% of patients having the pathology (i.e., current infection with HIV or susceptibility to infection with HIV; column 29). It is noted that the specification broadly describes what is intended to be encompassed by effective and stably effective. Thereby, "effective" and "stably effective" are considered to encompass any degree of response over any period of time. With respect to claim 7, the claim encompasses any form of indirect interaction between

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the compound and the target molecule. The ability of the compositions to bind to HBV proteins having mutations and to neutralize viral particles is considered to constitute modulation of a target molecule associated with a SNP.

**Response to Arguments:**

In the response filed December 17, 2004, Applicants did not specifically address this rejection. Accordingly, the rejection is maintained and made final for the reasons stated above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00

PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571)-272-0745.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers  
March 21, 2005

*Carla Myers*  
CARLA J. MYERS  
PRIMARY EXAMINER